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RJ1049
1 of 3

DOCKET NO. STEU-2418

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Taggart	)	Examiner: Tawfik, S.
	)	
Serial No.: 09/306,552	)	Art Unit: 3721
	)	
Filed: 05/06/99	)	

Title: **METHOD AND APPARATUS FOR ASEPTIC PACKAGING**

Commissioner for Patents
Washington, D.C. 20231

BRIEF OF APPELLANTS

Sir:

In accordance with 37 C.F.R. §§1.192 (a) and (c), the following Appeal Brief, pursuant to the Notice of Appeal filed July 9, 2001 in the above identified application, is an appeal from the final rejection of March 16, 2001.

REAL PARTY IN INTEREST

Steuben Foods, Incorporated is the real party in interest.

RELATED APPEALS AND INTERFERENCES

There are no other related appeals, interferences or applications which will direct or be directed by this appeal.

STATUS OF CLAIMS

Claims 1-17, 19, 21, and 35 stand finally rejected and are on appeal. They are set forth in the Appendix. Claims 18, 20 and 22-34 have been withdrawn from consideration, due to the restriction requirement in Paper No. 3, dated June 26, 2000.

STATUS OF AMENDMENTS

An After Final Response was filed on May 16, 2001. The response will be entered upon filing a Notice of Appeal and Appeal Brief as indicated in the May 31, 2001 Advisory Action. The After Final Response includes new claim 35.

SUMMARY OF INVENTION

The present invention relates to a method and device for aseptically bottling aseptically sterilized foodstuffs. The claims on appeal are directed to a method and device for aseptically bottling aseptically sterilized foodstuffs comprising the steps of: providing a plurality of bottles (page 12, line 8 - page 14, line 17); aseptically disinfecting the plurality of bottles to a level producing at least about a 6 log reduction in spore organisms (page 11, lines 4-9); filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs (page 29, line 9 - page 32, line 16) wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least about 12 log reduction in *Clostridium botulinum* (page 11, lines 1-3); and, filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute (page 7, line 21) wherein disinfecting the outside surfaces of the plurality of bottles is provided by hydrogen peroxide (page 14, lines 20-22; page 16, line 17 - page 19, line 11) further including

disinfecting the interior of the plurality of bottles with a hot hydrogen peroxide spray wherein the residual level of hydrogen peroxide is less than about .5ppm (page 7, lines 4-6; page 12, lines 3-7). The invention meets the various United States FDA aseptic standards and the 3A Sanitary Standards and Accepted Practices (page 4, lines 8-11; page 10, lines 18-22). The term "aseptic" as used in the invention denotes the United States FDA level of aseptic (page 3, lines 18-20; page 10, line 22 - page 11, line 1).

ISSUES

1. Whether claims 1-11, 16-19 and 21 are nonobvious under 35 U.S.C. §103(a) over Gies (U.S. 4,862,933), hereinafter "Gies", in view of Olsson (U.S. 5,799,464), hereinafter "Olsson".

2. Whether claim 12 is nonobvious under 35 U.S.C. §103(a) over Gies in view of Olsson further in view of Sizer *et al.* (U.S. 5,770,232), hereinafter "Sizer *et al.*".

3. Whether claims 13 and 14 are nonobvious under 35 U.S.C. §103(a) over Gies in view of Olsson further in view of B. Poole (U.S. 2,491,015), hereinafter "Poole".

4. Whether claim 15 is nonobvious under 35 U.S.C. §103(a) over Gies in view of Olsson further in view of Poole and Sizer *et al.*

GROUPING OF CLAIMS

Claims 1-19 and 21 are rejected. The grouping of the claims are:

I. Claims 1-12, 15-16, 18-19, and 21 stand or fall together;

II. Claims 13 and 14 stand or fall together;

III. Claim 17 stands or falls together; and

IV. Claim 35 stands or falls together.

ARGUMENT

Applicant respectfully submits that the rejections based on various combinations of Gies, Olsson, Sizer *et al.*, and Poole are defective because these references, taken alone, or in combination, fail to teach or suggest each and every feature of the claims as required by 35 U.S.C. §103. Further, Applicant respectfully submits that the Examiner has failed to present a *prima facie* case of obviousness in support of the rejection under 35 U.S.C. §103.

Briefly, the four patents cited by the Examiner are as follows: Gies discloses a doser for a sterilizer of a packaging system. Olsson discloses a method for aseptic and automatic transfer of unsealed pharmaceutical containers. Sizer *et al.* discloses a method of disinfecting the food contact surfaces of a food packaging machine and the disinfecting solution thereof. Poole discloses a method for sterilizing wooden produce baskets.

1. Claims 1-11, 16-19 and 21 are nonobvious over Gies and Olsson

Claims 1-11, 16-19 and 21 were rejected under 35 U.S.C. §103(a) as unpatentable over Gies in view of Olsson. See Paper No. 10.

Claim 1 presents a method for aseptically bottling aseptically sterilized foodstuffs comprising, *inter alia*, the steps of: "providing a plurality of **bottles**"; "**aseptically** disinfecting the plurality of **bottles** to a level producing at least **about a 6 log reduction in spore organisms**"; "filling the **aseptically** disinfected plurality of **bottles** with the **aseptically** sterilized foodstuffs; and, "filling ... at a rate greater than **100 bottles per minute**". Similarly, claim 13

also includes, *inter alia*, the step: "wherein disinfecting the **outside** surfaces of the plurality of bottles is provided by hydrogen peroxide". Claim 17 also includes, *inter alia*, the limitation "wherein the aseptically sterilized foodstuffs are sterilized to a level producing **at least about 12 log reduction in *Clostridium botulinum***". Claim 19 also includes, *inter alia*, the step "further including disinfecting the interior of the plurality of **bottles** with a hot hydrogen peroxide spray wherein the **residual level of hydrogen peroxide is less than about .5ppm**". Claim 35 discloses a combination of many of the aforementioned steps and limitations. Contrastingly, claim 21 discloses a device comprising, *inter alia*, means for providing a plurality of **bottles**; means for **aseptically** disinfecting the plurality of **bottles**; means for **aseptically** filling the **aseptically** disinfected plurality of **bottles** with the **aseptically** sterilized foodstuffs; and means for filling the **aseptically** disinfected plurality of **bottles** at a rate **great than 100 bottles per minute**. Neither Gies, Olsson, nor any of the other references cited by the Examiner, teaches or suggests these features. In particular, the combination does not disclose 1) aseptic or aseptically disinfecting; 2) these specific, measured levels of sterilization; 3) the bottling fill rates; and 4) the use of bottles or jars.

First, nowhere does Gies disclose, teach, or suggest either explicitly or inherently "aseptic" or "aseptically". Gies used the term "sterilize"(Col. 1, line 28), yet nowhere is the term defined. "Sterilize" in Gies appears to mean the generic cleaning *to some indeterminate level* of cleanliness. The closest Gies comes to providing a measured amount of sterilization is with the term "substantially sterile" (Col. 1, line 16). In contrast, the term "aseptic", as discussed throughout the invention, is clearly defined as meeting the strict definition of aseptic as promulgated by the United States Food and Drug Administration (page 10, line 22 - page 11, line

12), hereinafter "FDA". In order to meet the FDA definition of aseptic, the present invention must *inter alia* meet certain levels of cleanliness. Amongst the requirements to meet the FDA definition of aseptic the device must *inter alia* produce at least about a 12 log reduction of *Clostridium botulinum* in the food products (page 11, lines 1-12). Also, the packaging material must produce at least about a 6 log reduction of spores (page 11, lines 1-12). In the case of using hydrogen peroxide as the media, the test organism is *Bacillus subtilis var. globigii* (page 11; lines 1-12). The present invention attains the levels of cleanliness in order to meet the FDA definition of aseptic.

Second, the instant claims disclose specific measurable levels of sterilization, which heretofore, were not attainable in the prior art at the claimed bottle filling rates. These include aseptically disinfecting a plurality of bottles to a level producing at least about a 6 log reduction in spore organisms (page 11, lines 4-9) and sterilizing foodstuffs to a level producing at least about a 12 log reduction in *Clostridium botulinum* (page 11, lines 1-3). Additionally, the invention discloses a residual level of hydrogen peroxide remaining in the bottles of less than about .5ppm (page 12, lines 5-7).

Third, the instant claims disclose a specific bottle filling rate, which heretofore, was not attainable in the prior art at the claimed sterilization levels and residual levels of sterilant. Specifically, the invention can fill aseptically disinfected bottles at a rate greater than 100 bottles per minute (page 7, line 21) while still meeting the requirements of being aseptic.

The Examiner attempts to overcome these specific, measurable levels of sterilization by stating in the May 31, 2001 Advisory Action (Paper No. 10) that "aseptically disinfecting ... to a level producing at least about a 6 log or 12 log reduction in spore organisms would have been

obvious to one having ordinary skill in the art since Gies's reference discloses [disinfecting] (sic) aseptically the containers". Additionally, in the Final Office Action (Paper No. 8), dated March 16, 2001, the Examiner cites *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980), for the proposition that discovering an optimum value of a result effective variable involves only routine skill in the art. Respectfully, the specific levels of sterilization of the geometric configuration of bottles, the residual amount of sterilant in the bottles, and the bottling fill rate of greater than 100 **bottles** per minute is not anticipated or obviated by any of the prior art. Further, the ranges attainable by the prior art are not within, touching, or overlapping any of the disclosed, and claimed, ranges of sterilization levels, residual sterilant amounts, and bottling fill rates in the invention. Further, there is nothing in the cited prior art references which teach or suggest either explicitly or inherently how to increase sterilization levels, how to lower the residual sterilant amount, or how to speed up bottling rates. In other words, sterilization levels, residual sterilant amount, and bottling rate are not result effective variables. In order to alter these three variables to arrive at the claimed invention, *when taken together in combination*, would require undue experimentation by an artisan of ordinary skill in the art.

Fourth, the invention provides for the aseptic sterilization, and filling, of containers such as **bottles** or jars. The containers as disclosed, and claimed, include **bottles** with an opening size to height ratio of less than one (page 11, lines 13-17; see also claim 7). Filling bottles at the claimed fill rates is much more problematic for bottles than cups due to the difference in shape and geometry between bottles and cups (see page 5, line 21 - page 6, line 12).

The Examiner attempts to overcome the glaring deficiencies of Gies by relying on the reference to Olsson. In particular, the Examiner alleges "it would have been obvious to one with

ordinary skill in the art at the time the invention was made to have modified Gies's method for aseptically packaging aseptically sterilized foodstuffs by having containers made of glass or plastic bottles, as suggested by Olsson and because it has been held to be within the general skill of a work in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416*" (See Paper No. 8, page 3). Applicant strenuously disagree for several reasons.

The application of *In re Leshin* is inappropriate with the particular facts of this invention. *In re Leshin* pertained to the obvious substitution of plastic in lieu of metal as a suitable material for a common lip stick container. Substituting bottles for cups as the Examiner attempts to do by combining Olsson with Gies is not synonymous with *In re Leshin.* It is *both* the size, shape, and geometry, as well as, the material of the bottles used in the invention that *inter alia* distinguishes it over the use of cups, as disclosed in Gies. The interior surface of a bottle or jar is much more difficult to aseptically sterilize than the interior of a cup (page 5, lines 21-23). A sterilant can be introduced, activated, and removed in a cup much more rapidly than in a bottle or jar (page 6, lines 4-6). The processing speed when using a bottle or jar is limited, in part, by the time required to aseptically sterilized the interior surface of the bottle or jar (page 6, lines 6-9). Gies discloses a cup 15 which has an opening size larger when compared with the cup height (see Fig. 1). The substitution of bottles for cups is not an obvious material substitution. Heretofore, in both the Office Action (Paper No. 5), dated October 12, 2000, the Final Office Action (Paper No. 8), dated March 16, 2001, and the Advisory Action (Paper No. 10), dated May 31, 2001, the Examiner has *never* directly addressed the difference in size, shape, and geometry of **bottles** as in the invention vs. the use of cups. The Examiner has only cited *In re Leshin* as mentioned above

as to the reason for making an obvious combination of the use of **bottles** from Olsson with Gies. Further, there is no motivation or basis in Gies to suggest or teach the use of **bottles** in lieu of cups.

Additionally, there is neither suggestion nor teaching in Gies to combine using the bottles of Olsson. Without a suggestion or teaching, this is improper hindsight. Gies solely pertains to the application of sterilant in a packaging system using cups containing dairy products. Conversely, Olsson pertains to transporting open, filled pharmaceutical containers to a subsequent unit. There is no teaching or suggestion as to why the dairy cups in Gies would have to be transported to a second location, as in Olsson, prior to sealing. All the filling and sealing are completed within the packaging system of Gies.

Finally, by combining Olsson with Gies, Gies would be rendered inoperable. Gies discloses a packaging system for semiliquid materials, typically dairy-type foodstuffs, such as yogurt, butter, or pudding that are packaged in a cup that is sealed with a foil disk (Col. 1, lines 11-20). Both the packaging of these aforementioned products and the application of the sterilizing doser in Gies cannot work with a bottle. Gies only works with cups.

Thus, applicant respectfully requests reversal of the 35 U.S.C. §103(a) rejections of claim 1-11, 16-19 and 21.

2. Claim 12 is nonobvious over Gies, Olsson, and Sizer et al.

Claim 12 was rejected under 35 U.S.C. 103(a) as being unpatentable over Gies and Olsson, and further in view of Sizer *et al.*

Sizer *et al.* fails to overcome the aforementioned deficiencies. Thus, because claim 12 is

dependent upon claim 1, Applicant respectfully requests reversal of the 35 U.S.C. §103(a) rejection of claim 12.

3. Claims 13 and 14 are nonobvious over Gies, Olsson, and Poole

Claims 13 and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gies and Olsson, and further in view of Poole.

The Examiner rejected claims 13 and 14 under 35 U.S.C. 103(a) as being obvious based on Gies, in view of Olsson, further in view of Poole. The Examiner contends that Poole discloses a "method of sterilizing food containers from outside the food containers" (See Paper No. 8, page 6). This combination fails for several reasons.

First, the proposed modification of the Gies invention, with the sterilization of the outside of peach baskets from the Poole invention would render the Gies invention unsatisfactory for its intended purpose. Therefore, this makes the claimed invention nonobvious over this combination of citations (See *In re Gordon*, 733 F.2d 900 (Fed Cir. 1984)). Specifically, Gies would not work when combined with Poole. Poole discloses the full submersion of produced baskets in a liquid sterilant bath of indeterminate volume. In contrast, Gies involves a sterilant doser for sterilizing cups on a packaging line prior to being filled with dairy-type foodstuffs. A key feature of Gies is the application of "very accurate" dose of sterilant into the cup. "[I]t is essential that the amount used be very accurately dosed" (Col. 1, lines 40-45). Respectfully, there is simply no way that the sterilizing doser of Gies could work at all in the peach basket sterilant pool of Poole.

Second, there is neither a teaching nor suggestion either explicitly or inherently in the

prior art of Gies, Olsson, or Poole of the desirability of making the combination of Gies, Olsson, or Poole. Furthermore, the combination of Poole with Gies and Olssen would require the Examiner to improperly modify the secondary reference to Olssen to teach the outside of a bottle being sterilized. Respectfully, this is improper because the Examiner could continue modifying modified features *ad nauseam*. Such rejection is improper hindsight.

Furthermore, the combination of dairy-type food packaging of Gies as modified by pharmaceuticals packaging by Olssen and wooden produce baskets by Poole is clearly non-analogous. One of ordinary skill in the art would not be lead to these different fields of endeavor when trying to solve the problem of sterilizing the outside of bottles in aseptic sterilization the inventor was faced with. As evidence, the dairy-type foodstuffs industry of Gies is concerned with an accurate dosage of sterilant. Contrastingly, the produce delivering industry of Poole has no concern in applying an accurate dosage of sterilant.

The Examiner submits that reaching the levels of sterilization as specified in Claims 17-19 would be obvious to those skilled in the art because discovering optimal values of result effective variable (i.e. sterilization level) involves only routine skill in the art, *In re Boesch* (See Paper No. 8, page 4). There is nothing suggested in the teachings of Gies whereby a certain variable (i.e., sterilization level), or variables (i.e., sterilization level *and* speed of filling containers), can be adjusted to effect the variable(s) to their optimal level (or increased levels). Nor does Gies disclose how either of these variables can be improved. Those in the art would need to be informed on how to increase those variables rather than by just being told to keep trying. Furthermore, arriving at the claimed invention requires engineering which is more than routine experimentation. *In re Boesch* and *In re Aller, 105 USPQ 233*, stand for finding the

particular optimal value of a variable from within a given, known, obtainable range of the variable. Respectfully, the Applicant submits that what is disclosed, here in the claims and specification, is *inter alia* a method that produces values (i.e. sterilization levels and bottle filling rates) that clearly exceed previously obtainable values for those variables when taken together in combination.

Thus, Applicant respectfully requests reversal of the 35 U.S.C. §103(a) rejections of claims 13 and 14.

4. Claim 15 is nonobvious over Gies, Olsson, Poole and Sizer et al.

Claim 15 was rejected under 35 U.S.C. 103(a) as being unpatentable over Gies and Olsson, and further in view of Poole and Sizer *et al.*

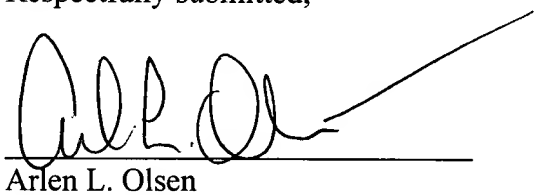
Both Poole and Sizer *et al.* fails to overcome the aforementioned deficiencies. Thus, because claim 15 is dependent upon claim 1, Applicant respectfully requests reversal of the 35 U.S.C. §103(a) rejection of claim 15.

It is this combination of elements and their limitations when taken in combination that distinguishes the claimed invention over other art. To date, there has been no patent(s), when take alone or in obvious combination, that disclose *inter alia* the claimed rate of filling of **bottles** with aseptic foodstuffs at the claimed specific **levels of sterilization**. Accordingly, in view of the above amendments and remarks, Applicant respectfully submits that the claims are allowable. Additionally, Applicant respectfully submits that new claim 35 is allowable, as well. Claim 18 was canceled, thus, the same number of claims are pending.

In summary, based upon the preceding arguments, Appellant respectfully believes that none of the applied references teach claims 1-17, 19, 21 and 35. Accordingly, Appellant respectfully requests reversal of the 35 U.S.C. §103(a) rejections of all claims.

Accordingly, Applicant submits that claims 1-17, 19, 21 and 35 are allowable.

Respectfully submitted,



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DOCKET NO.: **STEU-2418**

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(9) APPENDIX

CLAIMS ON APPEAL

1. A method for aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the plurality of bottles to a level producing at least about a 6 log reduction in spore organisms;

filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs; and

filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute.

2. The method according to claim 1, wherein the plurality of bottles are made from a glass.

3. The method according to claim 1, wherein the plurality of bottles are made from a plastic.

4. The method according to claim 3, wherein the plastic is polyethylene terepthalate.

5. The method according to claim 3, wherein the plastic is high density polyethylene.

6. The method according to claim 1, further including capping the bottle with an aseptically disinfected lid.

7. The method according to claim 1, wherein the plurality of bottles has an opening size to height ratio of less than one.

8. The method according to claim 1, further including disinfecting the interior of the plurality of bottles with a hot hydrogen peroxide spray.

9. The method according to claim 8, wherein disinfecting the interior of the plurality of bottles includes the application of the hot hydrogen peroxide spray for about 1 second and the activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air for about 24 seconds.

10. The method according to claim 1, further including a feedback control system for maintaining aseptic bottling conditions.

11. The method according to claim 1, wherein disinfecting is provided by hydrogen peroxide.

12. The method according to claim 1, wherein disinfecting is provided by oxonia.

13. The method for aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the plurality of bottles;

filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs; and

filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute wherein disinfecting the outside surfaces of the plurality of bottles is provided by hydrogen peroxide.

14. The method according to claim 13, wherein disinfecting the outside surface of the plurality of bottles includes about 1 second for the application of the hot hydrogen peroxide spray and about 24 seconds for the activation and removal of the hot hydrogen peroxide using hot aseptically sterilized air.

15. The method according to claim 1, wherein disinfecting the outside surfaces of the plurality of bottles is provided by oxonia.

16. The method according to claim 1, wherein the step of filling the aseptically disinfected bottling further comprises: filling the aseptically disinfected bottling at a rate greater than 360 bottles per minute.

17. The method for asepctically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least about 12 log reduction in *Clostridium botulinum*; and

filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute.

19. The method for aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs; and

filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute, further including disinfecting the interior of the plurality of bottles with a hot hydrogen peroxide spray wherein the residual level of hydrogen peroxide is less than about .5ppm.

21. A device for aseptically bottling aseptically sterilized foodstuffs having at least about a 12 log reduction in *Clostridium botulinum* comprising:

means for providing a plurality of bottles;

means for aseptically disinfecting the plurality of bottles;

means for aseptically filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs; and

means for filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute.

35. A method for aseptically bottling aseptically sterilized foodstuffs comprising the steps of:

providing a plurality of bottles;

aseptically disinfecting the plurality of bottles to a level producing at least about a 6 log reduction in spore organisms;

filling the aseptically disinfected plurality of bottles with the aseptically sterilized foodstuffs wherein the aseptically sterilized foodstuffs are sterilized to a level producing at least about a 12 log reduction in *Clostridium botulinum*; and

filling the aseptically disinfected plurality of bottles at a rate greater than 100 bottles per minute, further including disinfecting the interior of the plurality of bottles with a hot hydrogen peroxide spray wherein the residual level of hydrogen peroxide is less than about .5ppm.